GAMBRO Renal Products

510 (k) Summary

JAN 15 2002

PrismaSate

Dialysis Solutions for Continuous Renal Replacement Therapy

Contact Information:

GAMBRO Renal Products
1845 Mason Avenue
Daytona Beach, FL 32117
Phone: 386-274-2811
Fax: 386-274-2833
Contact: Fei Law

Prepared: October 10, 2001

510 (k) Summary

Name of the device: PrismaSate

Common Name: Dialysis Solutions for Continuous Renal Replacement Therapy
Ready to Use Sterile Dialysate

Classification Name: Dialysate Concentrate for Hemodialysis (Liquid or Powder) per 21 CFR 876.5820. The Product/Classification Code is KPO.

Predicate Devices: Premixed Dialysate for Hemodiafiltration
K910270 cleared 04/18/1991
Baxter Healthcare Corp.

Normocarb Sterile Bicarbonate Renal Dialysis Concentrate
K001059 cleared 06/30/2000
Dialysis Solutions, Inc. / Novex Pharma

Hemodialysis Bath Concentrate Solutions for Hemodialysis
K864265 cleared 03/17/1987
Dial Medical of Florida, Inc.

Dry AC Acid Concentrate Mix for Bicarbonate Hemodialysis
K011368 cleared 08/02/2001
Gambro Renal Products

Device Description:

Gambro PrismaSate solutions are sterile dialysate solutions for use in Continuous Renal Replacement Therapy (CRRT) for the treatment of acute renal failure and in other cases necessitating fluid or solute removal, such as in the case of drug poisoning with dialysable or filterable substances. The solutions are intended to be used in commercially available continuous renal replacement therapy machines as dialysate. A physician prescribes the chemical composition of the solution to be used.

The solutions are perfused through the dialysis fluid compartment of hemofilters/dialyzers. The dialysate is separated from the patient's blood by means of a semi-permeable membrane. Excess waste products, fluids and toxins found in the blood of a patient with acute renal failure pass through the membrane into the dialysate and eventually go to waste. The therapy is aimed at normalizing the blood.

CRRT is used for acute renal failure patients that may be too unstable to tolerate conventional hemodialysis, in which this function occurs much more rapidly (3-4 hours per treatment) and intermittently (3-6 times a week). In CRRT, the balancing is done on a continuous basis, 24 hours a day, in order to mimic kidney function.

Indications for Use: Gambro PrismaSate solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.

Comparison to Predicate Devices:

The Gambro PrismaSate Dialysate Solutions for Continuous Renal Replacement Therapy are equivalent to other dialysate products that are currently approved by the FDA, as demonstrated in the following table:

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	Intended Use	Chemical Composition	Sterility	Packaging
Gambro PrismaSate Dialysis Solutions for Continuous Renal Replacement Therapy	Dialysate for use in Continuous Renal Replacement Therapy.	Sodium 137 – 142 mEq/L Calcium 0 – 4 mEq/L Potassium 0 – 4 mEq/L Magnesium 0.5 – 1.5 mEq/L Bicarbonate 0 – 36 mEq/L Lactate 0 – 40 mEq/L Acetate 0 mEq/L Dextrose 0 – 2 g/L	Terminally Sterilized	PVC Bag
Baxter Healthcare Premixed Dialysate for Hemodiafiltration K 910270 Cleared 04/18/1991	For acute dialysis modalities that employ hemodiafiltration, such as continuous arteriovenous hemodialfiltration (CAVHD) and continuous venuous-venous hemodiafiltration (CWHD), when treatment of acute renal failure patients with hypervolemia and uremia requires high solute clearance	Sodium 140 mEq/L Calcium 3.5 mEq/L Potassium 2 mEq/L Magnesium 1.5 mEq/L Bicarbonate 0 mEq/L Lactate 30 mEq/L Acetate 0 mEq/L Dextrose 1 g/L	Terminally Sterilized	PVC bag
Dialysis Solutions, Inc. Novex Pharma Normocarb Sterile Bicarbonate Renal Dialysis Concentrate K 001059 Cleared 06/30/2000	Dialysate concentrate for use in hemodialysis. (Described as intended for use in Continuous Renal Replacement Therapy)	Sodium 140 mEq/L Calcium 0 mEq/L Potassium 0 mEq/L Magnesium 1.5 mEq/L Bicarbonate 35 mEq/L Lactate 0 mEq/L Acetate 0 mEq/L Dextrose 10.2 mEq/L (1.8 g/L)	Manufactured as a sterile product	Glass vials
Dial Medical of Florida Hemodialysis Bath Concentrate Solutions for Hemodialysis K 864265 Cleared 03/17/1987	Formulated to be used in conjunction with a Sodium Bicarbonate Concentrate in a three stream artificial kidney machine.	Sodium* 137 – 143 mEq/L Calcium 0 – 3.5 mEq/L Potassium 0 – 4 mEq/L Magnesium 0.5 – 1.5 mEq/L Bicarbonate* 32 – 36 mEq/L Lactate 0 mEq/L Acetate 3 – 4 mEq/L Dextrose 0 – 2 g/L	Not manufactured as a sterile product	PP/PE containers
Gambro Renal Products Dry AC Acid Concentrate Mix for Bicarbonate Hemodialysis K011368 Cleared 08/02/2001	For use with concentrated bicarbonate solution in 3-stream proportioning artificial kidney equipment using purified, AAMI standard water.	Sodium* 137 – 143 mEq/L Calcium 0 – 4 mEq/L Potassium 0 – 3 mEq/L Magnesium 0.5 – 1.5 mEq/L Bicarbonate* 32 – 36 mEq/L Lactate 0 mEq/L Acetate 3 – 4 mEq/L Dextrose 0 – 2 g/L	Not manufactured as a sterile product	PP/PE containers

*final dialysate concentration when mixed with sodium chloride/sodium bicarbonate buffer

Comparing the proposed device to the predicate devices, its ranges of chemical compositions, packaging, and sterility are equivalent to one or more of the predicate devices. Although the upper level of the lactate concentration is higher than the predicate devices, it is within the 30-60 mEq/L range specified by the European Pharmacopoeia Monograph for Solutions for Hemofiltration and Hemodiafiltration, an accepted reference standard. The primary function of the lactate is as a buffer. In this case, the higher lactate concentration brings the pH of the solution closer to the physiological plasma pH. There is no adverse effect on safety or effectiveness of the solution by offering a lactate concentration which is higher than the predicate devices. There are no significant differences in technological characteristics, and its intended use as dialysate is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2002

Ms. Fei Law
Quality Assurance Manager
Gambro Renal Products
1845 Mason Avenue
DAYTONA BEACH FL 32117

Re: K013448
Trade/Device Name: Gambro PrismaSate™ Dialysis Solutions for Continuous Renal Replacement Therapy
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: October 10, 2001
Received: October 17, 2001

Dear Ms. Law:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K013448

Device Name: PrismaSate™

Indications For Use:

Gambro PrismaSate™ solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013448

(Optional Format 3-10-98)